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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
CHENG, KAREN	

ART UNIT	PAPER NUMBER
1626	

DATE MAILED: 10/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/542,003	STURMER, RAINER	
	Examiner	Art Unit	
	Karen Cheng	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-9 is/are pending in the application.

4a) Of the above claim(s) 1 and 2 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 6,7 and 9 is/are rejected.

7)☒ Claim(s) 8 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 12 July 2005 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 7/12/05.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-9 are currently pending in the instant application.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

Lack of Unity Requirement

Claims 1-9 are drawn to more than one inventive concept (as defined by PCT Rule 13), and accordingly, a restriction is required according to the provision set forth in PCT Rule 13.2.

PCT Rule 13.2 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (requirement of unity of invention). PCT Rule 13.2 further states unity of invention as referred to in PCT Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. Special technical features, as defined in PCT Annex B, Part 1(b), include those technical features which define a contribution over the prior art.

PCT Annex B, Part 1(e) provides combinations of different categories of claims and states:

"The method for determining unity of invention under Rule 13.2 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:

(i) in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for a use of the said product, or

(ii) in addition to an independent claim for a given process, an independent claim for an apparatus or means specifically designed for carrying out the said process, or

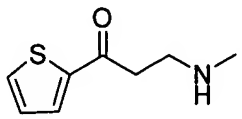
(iii) in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product and an independent claim for an apparatus or means specifically designed for carrying out the said process,..."

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Group I: Claims 1-2 drawn to the compound 3-methylamino-1-(2-thienyl)-1-propanone, and its acid addition salts and 3-methylamino-1-(2-thienyl)-1-propanone hydrochloride.

Group II: Claims 6-9 drawn to processes of preparation using said compound as an intermediate.

The structural moiety common to Groups I and II is 3-methylamino-1-(2-thienyl)-1-propanone.



This technical feature is not a special technical feature because it fails to define a contribution over the prior art (*see* DE 10240025.3 or US equivalent - US Pub.No. 2005/0261514). Therefore, Claims 1-9 are not so linked as to form a single general inventive concept, and there is lack of unity of invention.

Because the claims do not relate to a single general inventive concept under PCT Rule 13.1 and lack the same or corresponding special technical features, the

claims lack unity of invention and should be limited to a product, a process for the manufacture of said product, ***or*** a method of use.

Furthermore, with respect to **Groups I and II**, even if unity of invention under 36 CFR 1.475(a) is not lacking, a national stage application, under 37 CFR 1.475(b), containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn to only one of the following combinations:

(1) A product and a process specially adapted for the manufacture of said product; or
(2) A product and process of use of said product; or
(3) A product, a process specially adapted for the manufacture of said product, and a use of said product; or
(4) A process and an apparatus or means specially designed for carrying out said process; or
(5) A product, a process specially adapted for the manufacture of said product, and an apparatus or means specially designed for carrying out said process.

Moreover, according to 37 CFR 1.475(c), if an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b), unity of invention might not be present. As a result, the claims lack unity of invention and applicant is required to elect a single invention.

Election

During a telephone conversation with Applicant's Representative Ashley Pezzner on 10/06/2006 a provisional election was made *with traverse* to prosecute the invention of Group II, comprising Claims 6-9. Affirmation of this election must be made by applicant in replying to this Office action.

Applicant's traversal of the lack of unity requirement is not persuasive. As discussed in the lack of unity requirement, the compound 3-methylamino-1-(2-thienyl)-1-

propanone, its acid addition salts including the hydrochloride form, are known in the art (*see* DE 10240025.3 or US equivalent - US Pub.No. 2005/0261514). These compounds have been used to prepare other compounds, including duloxetine, fluoxetine and tomoxetine.

Information Disclosure Statement

Applicant's Information Disclosure Statement: filed on July 12, 2005 have been considered. Please refer to Applicant's copies of the 1449 submitted herewith.

Priority

This application is a 371 of International Application No. PCT/EP04/00237, filed on 1/15/2004, which claims the benefit of foreign priority under 35 U.S.C. 119, to German Application No. 10302595.2, filed on 1/22/2003. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Germany on 1/22/2003. It is noted, however, that applicant has not provided an English translation of the document as required by 35 U.S.C. 119(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 9 recites the limitation "as claimed in claim 1". There is insufficient antecedent basis for this limitation in the claim as claim 9 is drawn to a claim that has been withdrawn from consideration for being drawn to non-elected subject matter. It is suggested that applicant amend the claim so that it depends on the elected claims or is an independent claim.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as pertinent to the invention. Claim 6 contains the trademark/trade name Duloxetin. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not

comply with the requirements of 35 U.S.C. 122, second paragraph. See *Ex parte Simpson,* 218 USPQ 1020 (BD. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of good, and not the good themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a chemical compound, and accordingly, the identification/description is indefinite. The rejection can be overcome by, for example, deleting the claim or amending the claim to exclude the reference to the trademark name.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 6, 7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deeter et al, Tetrahedron Letters, **31**, 1990.

Applicants instant elected invention in claims 6, 7 teach preparation of (+)-(S)-N-methyl-3-(1-naphthyloxy)-3-(2-thienyl)-propylamine oxalate or an acid addition salt thereof through the reduction of 3-methylamino-1-(2-thienyl)-1-propanone, or an acid

addition salt thereof to (1S)-3-methylamino-1-(2-thienyl)propan-1-ol, or an acid addition salt thereof.

Applicants instant elected invention in claim 9 teach preparation of N-methyl-3-(1-naphthyloxy)-3-(2-thienyl)-propylamine or acid addition salts that comprises using 3-methylamino-1-(2-thienyl)-1-propanone, and its acid addition salts.

Determination of the scope and content of the prior art (MPEP §2141.01)

Deeter et al. teach the preparation of (+)-(S)-N-methyl-3-(1-naphthyloxy)-3-(2-thienyl)-propylamine oxalate through the intermediate 3-(dimethylamino)-1-(2-thienyl)-1-propanone, which is reduced to (1S)-3-(dimethylamino)-1-(2-thienyl)propan-1-ol, transformed into (+)-(S)-N-dimethyl-3-(1-naphthyloxy)-3-(2-thienyl)-propylamine oxalate, and dealkylated to give the desired product (See Deeter et al, p. 7102).

Deeter et al. also teach the preparation of (+)-(S)-N-methyl-3-(1-naphthyloxy)-3-(2-thienyl)-propylamine through the intermediate 3-(dimethylamino)-1-(2-thienyl)-1-propanone.

Ascertainment of the different between the prior art and the claims (MPEP §2141.02)

The difference between the prior art of Deeter et al and the instantly claimed compounds of 6, 7, and 9 is that Deeter et al inventions are directed to reduction and subsequent reaction of tertiary amine compounds rather than the secondary amine compounds claimed in the instant invention.

Finding of prima facie obviousness- rational and motivation (MPEP §2142-2143)

Deeter et al is analogous art because the compounds found in the art possess similar activity. In Ex part Bluestone, 135 USPQ 199, secondary and tertiary amines

are stated to be interchangeable. In the absence of unexpected results, one skilled in the art would expect that the instant claims which are analogous to Deeter et al compounds, i.e. secondary amine vs tertiary amine, is prima facie. The motivation to make the claimed compounds derives from the expectation that structurally similar compounds are generally expected to have similar properties and have similar utilities. In the instant case, the preparation of the secondary amine would be desirable since the compound of interest, duloxetin, contains a secondary amine. The explicit teaching of Deeter et al together with the enabled examples would have motivated one skilled in the art to modify the known compounds with such generic teaching with the expectation that they would all have similar activity as taught by Deeter et al.

Claim Objections

Claim 8 is objected to as being dependent upon a rejected base claim, but would appear allowable over the prior art of record if rewritten in independent form to include all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cheng whose telephone number is 571-272-6233. The examiner can normally be reached on M-F, 9AM to 5:30PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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